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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/054,665 | 01/22/2002 | John F. Engelhardt | 875.007US2 | 4004 |
| 21186 | 7590 | 06/16/2004 | EXAMINER | |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402 | | | GUZO, DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |
| DATE MAILED: 06/16/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,665

Applicant(s)

ENGELHARDT ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/22/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

The Restriction Requirement mailed 2/24/04 was incorrectly based upon what appeared to be pending claims 1-39. Claims 1-39 had been cancelled by applicants in an amendment filed 6/25/02 and new claims 40-60 added. The Restriction Requirement is therefore withdrawn. An Office Action on claims 40-60 follows.

Sequence Rules Compliance

Nucleotide sequences present in Figures 2C and 11 and not identified by SEQ ID NO in the Figures themselves or in the Brief Description of the Drawings section of the specification. Applicants must amend the specification or submit substitute drawings identifying the nucleotide sequence by the appropriate SEQ ID NO identifier so as to comply with the Sequence Rules (37 CFR 1.821-1.825). Any response to this Office Action that does not include full compliance with the Sequence Rules will be considered non-responsive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-42, 44-48, 50-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,436,392 (hereafter the '392 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same AAV compositions and use of said compositions to express gene products in animal (mammalian) cells. The instant claims differ from those of the '392 patent in that they are broader with regard to reciting AAV vectors (and methods of use of said vectors to express a gene of interest in a host cell) comprising **nucleic acid segments** (rather than **DNA segments** of the '392 claims) and reciting AAV vectors comprising a gene to be expressed which includes a **transcriptional regulatory region** rather than a "**promoter**" as recited in the '392 patent. However, the instant claims are generic to those recited in the '392 patent. Claims reading on AAV vectors comprising nucleic acids are generic to AAV vectors comprising DNA sequences and claims reading on AAV comprising transcriptional regulatory regions operably linked to a gene of interest are generic to AAV vectors comprising promoters operably linked to a gene of interest. The claims of the '392 patent would anticipate the instant invention.

Claims 43 and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7-9 of U.S. Patent No. 6,436,392 in view of Natsoulis et al. (US 5,843,742).

Applicants claim recombinant AAV vector compositions comprising first and second AAV vectors, each of which contains a portion of a heterologous gene of interest wherein after trans-splicing in a host cell a functional gene encoding a functional polypeptide is produced and applicants claim a method for expressing a polypeptide in a host cell. The claims in the '392 patent recite the same compositions and methods with the exception that the 5' portion of the heterologous gene of interest contains a transcriptional regulatory region and an enhancer.

Natsoulis et al. (US 5,843,742, issued 12/1/98, filed 9/8/95, see whole document, particularly column 7, lines 23-27; column 10, lines 15-26) teaches that incorporation of enhancer elements in AAV vectors are routinely included to direct expression of the gene of interest carried in the vector.

The ordinary skilled artisan, seeking to generate trans-splicing AAV vectors capable of expressing a gene of interest would have been motivated to include an enhancer element in the AAV vectors disclosed in the '392 patent because Natsoulis et al. teaches that enhancer elements are routinely included in AAV vectors for their expected benefit of influencing expression of a heterologous gene of interest that they are operably linked to. It would have been obvious to do this because enhancer elements are standard expression control elements that are routinely included in AAV vectors (as taught by Natsoulis et al.) for their known benefit of increasing expression of the gene of interest. Given the state of the art and the level of skill of the ordinary skilled artisan at the time of applicants' invention, said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The closest prior art is exemplified by McVey et al. (US 5,801,030) and Mitchell et al. (US 6083,702, cited by applicants). While the prior art teaches spliceosome mediated RNA splicing, the art does not teach or suggest use of trans-splicing in the context of generating a functional gene from gene segments divided in two AAV vectors.

The Drawings filed 1/22/02 are objected to. Figures 2A-B, 3A-B, 4A-B, 5B, 7A, 8B, 13, 15A-D, 17A-C and 18C are so dark in portions as to be uninterpretable. Numbers, letters and reference characters in Figure 2C are not 1/8 inch in height.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for


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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
June 9, 2004


DAVID GUZO
PRIMARY EXAMINER